

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 36

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte RONALD M. EVANS, MICHAEL B. MC KEOWN,
ANTHONY E. ORO, WILLIAM A. SEGRAVES, and TSO-PANG YAO

Appeals No.1997-2325
Application No. 08/486,403

ON BRIEF

Before, WILLIAM F. SMITH, SPIEGEL, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-7 and 35-44, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. An isolated multimeric receptor, wherein at least one subunit of said multimeric receptor is an ultraspiracle receptor, and wherein at least one subunit of said multimeric receptor is a hormone binding protein; wherein said hormone binding protein is characterized by having a DNA-binding domain having the amino acid sequence set forth in SEQ ID NO: 3.

GROUND OF REJECTION¹

Claims 1-7 and 35-44 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

We reverse.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's Answer² for the examiner's reasoning in support of the rejection. We further reference appellants' Brief³ for the appellants' arguments in favor of patentability.

¹ We note the examiner withdrew (Answer, page 5) the rejection of claims 1-7 and 35-44 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

² Paper No 34, mailed December 9, 1996.

³ Paper No. 33, received October 4, 1996.

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

The examiner bears the initial burden of providing reasons why a supporting disclosure does not enable a claim. In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

The examiner finds (Answer, page 4) that “in order to practice the claimed invention, the skilled artisan need be reasonably able to predict not only the amino acid residue sequence of the hormone binding protein ... but the skilled artisan would also need to have reasonable guidance as to what other amino acid sequences would work.” The examiner points out (Answer, bridging paragraph pages 4-5) that “SEQ ID NO:3 [of the specification] clearly shows that 48 of the 71 amino acids are unknown [and therefore] ... the skilled artisan ... would have to screen 48²⁰ ... different compounds ... such efforts would rise to the level of undue experimentation.”

Appellants argue (Brief, page 11) that:

Appellants have provided in the specification the entire sequence of an ultraspiracle receptor ... [a]dditionally ... determining which amino acid residues, when present in the X positions in SEQ ID NO:3, result in functional receptors ... is largely irrelevant, as it is the identity and the position of the specified amino acids (i.e., those other than X) that are required for a protein to be a functional member of the steroid/thyroid superfamily of receptors [emphasis in original].

In response to appellants' argument the examiner states (Answer, page 6) that “[t]he substitution of a single amino acid can have a profound effect on the charge, affinity, and conformation of the protein; such features go to the heart of the claimed invention.”

The issue raised by the examiner is whether one skilled in the art could make and use the claimed invention throughout its scope without undue experimentation.

As explained in PPG Indus., Inc. v. Guardian Indus. Corp.,

75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996):

In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation “must not be unduly extensive.” Atlas Powder Co., v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeals summarized the point well when it stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 USPQ 804, 807 (1982).

As stated by appellants (Brief, page 11) “[a]ppellants need not define exactly those combinations of amino acids that yield a functional receptor when present in the X positions, as those combinations, if any, that are not functional are outside the scope of the claims [emphasis in original].” Here, all the examiner has established is that some experimentation would be required to make and use other

embodiments of the claimed invention. What the examiner has not done is perform the fact-finding needed in order to reach a proper conclusion of undue experimentation. The examiner has not relied upon any evidence in support of this rejection which would establish that making and testing other sequences beyond those described in the present specification amounts to undue experimentation.

The examiner's unsupported conclusions do not suffice.

Accordingly, the rejection of claims 1-7 and 35-44 under 35 U.S.C. § 112, first paragraph is reversed.

REVERSED

William F. Smith)	
Administrative Patent Judge)	
)	
)	
)	BOARD OF PATENT
Carol A. Spiegel)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
)	
Donald E. Adams)	
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Stephen E. Reiter

Appeal No. 1997-2325
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